

# **ABSTRACT**

## **BACKGROUND**

Diabetic neuropathy is a common complication that develops in nearly 50% of over all diabetes population especially long standing hyperglycemic patients. Diabetic neuropathy appears relatively early in the disease process. The prevalence of upto 7% is reported in South Indian patients even at the time of diagnosis of diabetes. Though precise mechanism of neuronal damage is unclear, accumulation of excess sorbitol through polyol pathway is supportive evidence. Recently Epalrestat and Methylcobalamin are widely used in clinical practice to manage diabetic neuropathy. This study was aimed to compare the efficacy and safety of Epalrestat with Methylcobalamin in patients with diabetic neuropathy.

## **PATIENTS AND METHODS:**

A total number of 165 patients with diabetic neuropathy were included in this study. The patients were divided into three groups; group A was administered with 150 mg of Epalrestat alone, group B was administered with 1500 mcg of Methylcobalamin alone, Group C was administered with 150 mg of Epalrestat + 1500 mcg Methylcobalamin in combination once daily basis. The treatment period was 12 weeks with monitoring on week 4, 8 & 12 of the study. At base line and at follow up visits following parameters were evaluated: pain intensity by VAS pain score, loss of sensation, burning sensation, numbness, muscle cramps, spontaneous pain, weakness, dizziness, loss of sensation of heat &

cold assessed by Michigan Neuropathy Screening Instrument score method (MNSI) & HbA1C.

## **RESULTS:**

All the parameters were improved in three groups compared to baseline screening. In group C significant ( $p<0.001$ ) reduction in pain score (3.09) was observed at 8<sup>th</sup> week onwards while compared to baseline and very good reduction in pain score was observed at 12<sup>th</sup> week of therapy. All three groups had significant ( $p<0.001$ ) reduction in MNSI score, especially group C were shown to have very good reduction compared to the rest other groups. With respect to HbA1C, both group A & C were shown equal amount (7.56%) of reductions compared to group B.

## **CONCLUSION:**

Combination of Epalrestat and Methylcobalamin was more efficacious, well tolerated and safer with safety for the management of diabetic neuropathy than monotherapy of Epalrestat and Methylcobalamin. The combination therapy showed better improvement of symptoms of Diabetic neuropathy

## **KEYWORDS:**

Diabetic neuropathy, Epalrestat, Methylcobalamin, Michigan Neuropathy Screening Instrument (MNSI), Visual Analog Scale (VAS).